



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2011-0593; FRL-9358-3]

Flumioxazin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of flumioxazin in or on multiple commodities which are identified and discussed later in this document. Valent U.S.A. Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2011-0593, is available either electronically through <http://www.regulations.gov> or in hard copy at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in EPA West, Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone

number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Bethany Benbow, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 347-8072; email address: benbow.bethany@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2011-0593 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2011-0593, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information

you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), Mail Code: 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of August 26, 2011, 76 FR 53374 (FRL-8884-9), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1F7886) by Valent U.S.A. Corporation, 1600 Riviera Ave., Suite 200, Walnut Creek, CA 94596. The petition requested that 40 CFR 180.568 be amended by establishing tolerances for residues of the herbicide, flumioxazin, 2-[7-fluoro-3,4-dihydro-3-oxo-4-(2-propynyl)-2H-1,4-benzoxazin-6-yl]-4,5,6,7-tetrahydro-1H-isoindole-1,3(2H)-dione, in or on Pea and bean, dried shelled (except soybean), crop subgroup 6C at 0.1 parts per million (ppm); Rapeseed, crop subgroup 20A at 0.35 ppm for seed, 0.04 ppm for meal, and 0.02 ppm for refined oil; Sunflower, crop subgroup 20B at 0.5 ppm for seed, 0.03 for meal, 0.02 ppm for refined oil; and Wheat at 0.35 ppm for grain, 5.0 ppm for straw, 0.02 ppm for forage, 0.02 ppm for hay, 0.35 ppm for bran, 0.05 ppm for flour, 0.35 ppm for germ, 0.08 ppm for middlings, 0.11 ppm for shorts, 110 ppm for aspirated grain fractions. In addition, the petition requested revocation of the existing

tolerance for residues of flumioxazin in or on beans, dry seed, if a tolerance for Crop subgroup 6C (which includes this commodity) is set as requested. That notice referenced a summary of the petition prepared by Valent U.S.A. Corporation, the registrant, which is available in the docket, EPA-HQ-OPP-2011-0593 at <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition and use of the OECD tolerance calculation procedures, EPA has determined that a single tolerance to cover all of the commodities within each of the crop subgroups is appropriate versus individual tolerances for each of the commodities within the crop subgroups. In addition, EPA has determined that several of the proposed tolerances for wheat commodities, including wheat bran, flour, germ, middlings, and shorts, are not required. The reason for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a

reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for flumioxazin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with flumioxazin follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. A summary of the toxicological findings are as follows:

Flumioxazin has mild or low acute toxicity when administered orally, dermally, or by inhalation. It is not an eye or skin irritant, or a dermal sensitizer. In general, the subchronic and chronic toxicity studies demonstrated that toxic effects associated with flumioxazin include anemia as well as effects on the liver and the cardiovascular system. Developmental effects were observed in developmental rat studies but not in developmental rabbit studies. Hematologic (hematopoietic) effects of anemia were noted in rats, consisting of alterations in hemoglobin parameters. Increased renal toxicity in male rats was also reported following chronic exposure. There is no evidence of neurotoxicity or immunotoxicity in the recently submitted guideline studies. Increased

quantitative susceptibility was seen in the rat developmental toxicity studies. Fetal effects were observed in the absence of maternal toxicity. In addition, both increased qualitative and quantitative susceptibility were observed in the rat reproduction study. Severe fetal effects were observed at lower doses than milder parental effects. In most of the available mutagenicity studies, flumioxazin was negative for mutagenicity; however, aberrations were seen in a chromosomal aberration assay (CHO cells). Based on the lack of evidence of carcinogenicity in mice and rats, flumioxazin is classified as “not likely to be carcinogenic to humans.”

Specific information on the studies received and the nature of the adverse effects caused by flumioxazin as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in the document, *Flumioxazin. Human Health Risk Assessment for the Proposed Uses on Wheat, Sunflower, Safflower, Flax, Lentils and Field Peas* on page 20 in docket ID number EPA-HQ-OPP-2011-0593.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors (U/SF) are

used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see

<http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for flumioxazin used for human risk assessment is shown in Table 1 of this unit.

Table 1.—Summary of Toxicological Doses and Endpoints for Flumioxazin for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (Females 13-50 years of age)	NOAEL = 3 mg/kg/day $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	Acute RfD = aPAD = 0.03 mg/kg/day	Oral Developmental and Supplemental Pre-natal Studies (Rat) LOAEL = 10 mg/kg/day, based on cardiovascular effects in fetuses.
Acute dietary (General population including infants and children)	No appropriate toxicological effects attributable to a single exposure (dose) were observed in oral toxicity studies including maternal effects in developmental studies in rats and rabbits. Therefore, a dose and endpoint were not identified for this risk assessment.		
Chronic dietary (All populations)	NOAEL= 2.0 mg/kg/day $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	Chronic RfD= cPAD = 0.02 mg/kg/day	2-Year Chronic/Carcinogenicity Study (Rat) LOAEL = 18 mg/kg/day, based on increased chronic nephropathy in males and decreased hematological parameters in females.
Incidental oral short-term (1 to 30 days) and	NOAEL= 6.3 mg/kg/day $UF_A = 10x$	LOC for MOE = 100	2-Generation Reproduction Study (Rat) LOAEL = 12.7 mg/kg/day,

intermediate-term (1 to 6 months)	UF _H = 10x FQPA SF = 1x		based on decreased pup body weight and testicular atrophy in F1 males.
Dermal-Children short-term (1 to 30 days) and intermediate-term (1 to 6 months)	NOAEL = 6.3 mg/kg/day (dermal absorption factor = 8%) UF _A = 10x UF _H = 10x FQPA SF = 1x	LOC for MOE = 100	2-Generation Reproduction Study (Rat) LOAEL = 12.7 mg/kg/day, based on decreased pup body weight and testicular atrophy in F1 males.
Dermal-Adults All Durations	NOAEL = 30 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	LOC for MOE = 100	Dermal Developmental Study (Rat) LOAEL = 100 mg/kg/day, based on cardiovascular effects in fetuses.
Inhalation short-term (1 to 30 days) and Intermediate term (1 to 6 months)	oral study NOAEL = 3 mg/kg/day (inhalation absorption rate = 100%) UF _A = 10x UF _H = 10x FQPA SF = 10x UF _{DB}	LOC for MOE = 1000	Oral Developmental Study (Rat) LOAEL = 10 mg/kg/day, based on cardiovascular effects in fetuses.
Inhalation Long-term (> 6 months)	NOAEL = 2 mg/kg/day (inhalation absorption rate = 100%) UF _A = 10x UF _H = 10x FQPA SF = 10x UF _{DB}	LOC for MOE = 1000	2-Year Chronic/Carcinogenicity Study (Rat) LOAEL = 18 mg/kg/day, based on increased chronic nephropathy in males and decreased hematological parameters in females.
Cancer (Oral, dermal, inhalation)	“Not likely to be a carcinogenic to humans,” based on the lack of carcinogenicity in a 2-year rat study, an 18-month mouse study, and a battery of mutagenic studies.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_{DB} = to account for the absence of data or other data deficiency. UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to flumioxazin, EPA considered exposure under the petitioned-for tolerances as well as all existing flumioxazin tolerances in 40 CFR 180.568. EPA assessed dietary exposures from flumioxazin in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Such effects were identified for flumioxazin. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed residues are present in all commodities at the tolerance level and that 100% of commodities with tolerances are treated with flumioxazin. In addition, EPA used default concentration factors to estimate residues of flumioxazin in processed commodities. Acute dietary exposure was only estimated for females 13-49 years old based on cardiovascular effects in fetuses observed in the oral developmental and supplemental pre-natal rat studies. An endpoint of concern was not established for acute dietary assessment of the general population.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994-1996 and 1998 CSFII. As to residue levels in food, EPA assumed residues are present in all commodities at the tolerance level and that 100% of commodities with tolerances are treated with

flumioxazin. In addition, EPA used default concentration factors to estimate residues of flumioxazin in processed commodities.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that flumioxazin does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk was not conducted.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for flumioxazin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of flumioxazin. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Modeled estimates of drinking water concentrations, based on the estimated environmental concentrations (EECs) for flumioxazin and its major degradates (482-HA and APF) under the use as an aquatic herbicide, were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 400 parts per billion (ppb) was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 142 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure*. The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Flumioxazin is currently registered for the following uses that could result in residential exposures: Aquatic areas, ornamental gardens, ornamental trees, and turf in residential

lawns, athletic fields, parks, and golf courses. EPA assessed residential exposure with the assumption that homeowner handlers wear shorts, short-sleeved shirts, socks, and shoes, and that they complete all tasks associated with the use of a pesticide product including mixing/loading, if needed, as well as the application. Residential handler exposure scenarios for both dermal and inhalation are considered to be short-term only, due to the infrequent use patterns associated with homeowner products. EPA uses the term “post-application” to describe exposure to individuals that occur as a result of being in an environment that has been previously treated with a pesticide. Flumioxazin can be used in many areas that can be frequented by the general population including residential areas, golf courses, lakes, and ponds. As a result, individuals can be exposed by entering these areas if they have been previously treated. Therefore, short-term and intermediate dermal post-application exposures and risks were assessed for adults and children. In addition, oral post-application exposures and risks were assessed for children to be protective of possible hand-to-mouth, object-to-mouth, and soil ingestion activities that may occur on treated turf areas. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

4. *Cumulative effects from substances with a common mechanism of toxicity.*

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.” EPA has not found flumioxazin to share a common mechanism of toxicity with any other substances, and flumioxazin does not appear to

produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that flumioxazin does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* Evidence of increased susceptibility to fetuses was observed in the oral and dermal developmental rat studies [i.e. cardiovascular anomalies (ventricular septal defect)] that occurred in the absence of maternal toxicity. Additionally, the rat reproduction study demonstrated evidence of qualitative and quantitative post-natal susceptibility because reproductive effects in offspring were observed at doses lower than those that caused parental/systemic toxicity, and because the reproductive effects in offspring were considered to be more severe than the parental/systemic effects.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X for oral and dermal exposures, but be retained at 10X for inhalation exposures. That decision is based on the following findings:

i. The toxicity database for flumioxazin is largely complete with the exception of an inhalation developmental study, which was recently determined necessary, in order to better assess route-specific inhalation risks. In the absence of this study, a 10x FQPA safety factor to account for database uncertainty is needed to protect the safety of infants and children to assess risks for all inhalation exposure scenarios. The toxicity profile can be characterized for all effects, including potential developmental and reproductive toxicity, immunotoxicity and neurotoxicity with the current database.

ii. There is no indication that flumioxazin is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. Although increased susceptibility was seen in the rat developmental and reproductive studies, EPA's concern for these effects is low, and there are no residual uncertainties for pre- and/or postnatal toxicity because: The developmental toxicity NOAELs/LOAELs are well characterized after oral and dermal exposure; the offspring toxicity NOAEL and LOAEL are well characterized in the reproduction study and; the Points of Departure (POD) for assessing risk to developing fetuses, infants, and children have been selected either from the developmental and reproductive toxicity studies from the chronic study which established a lower POD for chronic effects than the studies in pre- and postnatal animals. Thus, the regulatory endpoints for flumioxazin are protective

of the increased susceptibility seen in the developmental and reproduction studies, and there are no residual concerns for these effects.

iv. There are no residual uncertainties identified in the exposure databases. Because the acute and chronic dietary exposure estimates were based on several conservative assumptions (100% of crops treated with residues present at tolerance levels, default processing factors and screening level drinking water estimates), EPA is confident that the dietary exposure assessments do not underestimate risk to the general U.S. population and various population subgroups. Similarly, EPA does not believe that the non-dietary residential exposures are underestimated because they are based on the conservative assumptions of EPA's Draft Standard Operating Procedures (SOPs) for Residential Exposure Assessments (December 1997), and updates contained in the Science Advisory Council Policy 12 (February 2001) as well as the uses specified in the proposed labels.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Acute aggregate risk takes into account exposure to residues in food and drinking water alone. Therefore, acute aggregate risk is equivalent to the acute dietary risk as discussed in Unit III.C.1.i. The acute dietary exposure estimate for

females 13-49 years old will utilize 68% of the aPAD, which is below the Agency's LOC (100% of the aPAD).

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to flumioxazin from food and water will utilize 54% of the cPAD for all infants (< 1 year old) the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of flumioxazin is not expected.

3. *Short-term risk.* Flumioxazin is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to flumioxazin.

Different methodologies were used for the presentation of short-term aggregate risk for adults and children. An aggregate risk estimate (ARI) approach was required to estimate short-term adult aggregate risk because there are different LOCs for adult dermal and inhalation exposures, 100 and 1,000, respectively. For short-term child aggregate risk, the combined MOE approach was used because the endpoint of concern (decreased pup weight) and the LOC are the same. Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate ARI of 1.15 for adults and aggregate MOE of 150 for children. Because EPA's LOC for flumioxazin is an ARI of 1 or below and a MOE of 100 or below, these aggregate risk estimates are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Since the short- and intermediate-term toxicological endpoints for flumioxazin are the same for each route of exposure, only short-term exposures were assessed.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, flumioxazin is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to flumioxazin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography/nitrogen-phosphorus detection (GC/NPD) method, Valent Method RM30-A-1) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA

section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. There are no MRLs established by Codex, Canada, or Mexico for any of the proposed commodities in the current registration actions.

C. Revisions to Petitioned-For Tolerances

EPA has revised the requested tolerances by adjusting the tolerance values, substituting crop group tolerances for individual tolerances, and dropping unnecessary tolerances. The tolerance levels were revised based on analysis of the field trial data using the Organization for Economic Cooperation and Development (OECD) tolerance calculation procedures. EPA believes they differ from the petitioner's proposed tolerances for dried pea, rapeseed subgroup 20A, and wheat grain and straw due to the petitioner having possibly used the National Technology Transfer and Advancement Act of 1995 (NAFTA) tolerance calculation procedures as opposed to the OECD procedure. In addition, EPA is setting single tolerances for the crop subgroups (6C, 20A and 20B) versus individual tolerances for each commodity within the subgroups since maximum residues of the commodities within the crop subgroups differ by less than 5X. The proposed tolerances for wheat commodities (bran, flour, germ, middlings, and shorts) are also not necessary since they are covered by the tolerance being set for wheat grain.

V. Conclusion

Therefore, tolerances are established for residues of flumioxazin, 2-[7-fluoro-3,4-dihydro-3-oxo-4-(2-propynyl)-2 *H* -1,4-benzoxazin-6-yl]-4,5,6,7-tetrahydro-1 *H* -isoindole-1,3(2 *H*)-dione, including its metabolites and degradates, in or on the commodities as set forth in the regulatory text. Compliance with the tolerance levels specified below is to be determined by measuring only flumioxazin.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of NTTAA, Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United

States prior to publication of this final rule in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 10, 2012.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Section 180.568 is amended by:

a. Alphabetically adding the following commodities to the table in paragraph (a);

. b. Removing the commodity, “bean, dry seed” from the table in paragraph (a).

The amendments read as follows:

§ 180.568 Flumioxazin; tolerances for residues.

(a) * * *

Commodity	Parts per million
* *	* * *
Grain, aspirated fractions	100
* *	* * *
Pea and bean, dried shelled, except soybean, subgroup 6C	0.07
* *	* * *
Rapeseed subgroup 20A	0.40
* *	* * *
Sunflower subgroup 20B	0.50
* *	* * *
Wheat, forage	0.02
Wheat, grain	0.40
Wheat, hay	0.02
Wheat, straw	6.0

* * * * *